Exhibit A

Service

IN THE 22ND JUDICIAL CIRCUIT COURT, CITY OF ST LOUIS, MISSOURI

Judge or Division: MICHAEL KELLAN MULLEN	**Case Number: 1722-CC10695**	Special Process Server 1
Plaintiff/Petitioner: JONATHAN RASKAS **vs.**	Plaintiff's/Petitioner's Attorney/Address FRANCIS JOSEPH FLYNN Jr STE 1100 8235 FORSYTH SAINT LOUIS, MO 63105-1643	Special Process Server 2 Special Process Server 3
Defendant/Respondent: TEVA PHARMACEUTICALS USA INC	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101	
Nature of Suit: CC Wrongful Death		(Date File Stamp)

Summons in Civil Case

The State of Missouri to: TEVA PHARMACEUTICALS USA INC
Alias:
CORP CREATIONS NETWORK INC
12747 OLIVE BLVD 300
SAINT LOUIS, MO 63141

ST LOUIS COUNTY SHERIFF

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

June 30, 2017
Date

Thomas Kloeppinger
Clerk

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to _____ (name) _____ (title).

☐ other _____.

Served at _____ (address)

in _____ (County/City of St. Louis), MO, on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____ Date

_____ Notary Public

Sheriff's Fees

Summons	$_____
Non Est	$_____
Sheriff's Deputy Salary	
Supplemental Surcharge	$ 10.00
Mileage	$_____ (_____ miles @ $._____ per mile)
Total	$_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT
ST. LOUIS CITY

JONATHAN RASKAS, personally and as administrator of the ESTATE OF RALPH RASKAS **Plaintiff,** **v.** TEVA PHARMACEUTICALS USA, INC., Serve: TEVA PHARMACEUTICALS USA, INC. c/o CORPORATE CREATIONS NETWORK INC. 12747 Olive Blvd. #300 Saint Louis, MO 63141 ACTAVIS ELIZABETH LLC, Serve: 200 Elmora Avenue, Elizabeth, New Jersey 07202 and JOHN DOE DEFENDANTS, **Defendants.**	**CAUSE NO.** 1722-CC10695 **JURY TRIAL DEMANDED**

PETITION

COMES NOW, Plaintiff Jonathan Raskas, personally and as administrator of the Estate of Ralph Raskas, and by and through his undersigned attorney, and alleges upon personal knowledge as to Plaintiff's individual actions and upon information and belief and/or counsel's investigations as to all other matters as follows:

Nature of the Action

1. Plaintiff brings this action against Teva Pharmaceuticals USA ("Teva") and Actavis Elizabeth LLC ("Defendants") (a) for personal injuries Ralph Raskas suffered before his death as a direct and proximate result of being exposed to the drug Reglan/metoclopramide; and (b) for his wrongful death which were a direct and proximate result of being exposed to the prescription drug Reglan/metoclopramide.

2. As a result of the harmful and defective nature of Reglan/metoclopramide, Ralph Raskas ("Plaintiff's Decedent") was severely and permanently injured to such a degree that it directly and proximately caused or contributed to cause Ralph Raskas wrongful death.

PARTIES

3. At all relevant times, Plaintiff Jonathan Raskas is and was a resident of Saint Louis in the State of Missouri, in the United States of America. Plaintiff Jonathan Raskas was the father of Ralph Raskas who tragically took his life as a result of his use of Reglan / metoclopramide. He brings this action personally and as administrator of the Estate of Ralph Raskas.

4. Jonathan Raskas, personally, is a proper party under the Missouri Wrongful Death Statute RSMo. 537.080 to bring an action for the death of Ralph Raskas by reason of the wrongful acts of the Defendants named herein. Jonathan Raskas, in his capacity as administrator of the Estate of Ralph Raskas, is a proper party under RSMo. 516.180 to bring those causes of action that survive Ralph Raskas.

DEFENDANTS

5. Defendant Teva Pharmaceuticals USA, Inc., is a Delaware corporation that regularly conducts business in St. Louis City, Missouri. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below.

6. Defendant Actavis Elizabeth LLC is a Delaware corporation with a principal place of

business in New Jersey. Defendant regularly conducts business in St. Louis City, Missouri. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below.

7. The John Doe Defendants are defendants involved in the manufacture, distribution, marketing, sale, and labeling of Reglan and/or metoclopramide not yet known by Plaintiff.

JURISDICTION AND VENUE

8. Jurisdiction is proper here in that defendants do business in the State of Missouri. Defendants marketed and sold their product in Missouri.

9. There is no federal subject matter jurisdiction because no federal question is raised.

10. Venue is proper in this Court pursuant to the court's order of August 8, 2012 in the original case, *Jannett Anderson, et al., v. Wyeth, LLC., et al.*, Cause No. 1222-CC00910.

Factual background

11. Ralph Raskas was born in 1996 in St. Louis, Missouri. He was an honor student at Clayton High School. Growing up in St. Louis he did not have history or receive treatment for mental illness. He was admitted to a six (6) year medical school program at University of Missouri, Kansas City. After completing his first year at UMKC, he was fully prepared to return in the fall for his second year of studies.

12. On May 9, 2015, Ralph Raskas presented to the emergency room at St. Luke's Hospital of Kansas City, Missouri with nausea and vomiting. He was 19 at the time.

13. On that day at the emergency room at St. Luke's Hospital of Kansas City, 5 milligrams of Teva Pharmaceutical Industries Ltd. ("Teva") manufactured metoclopramide was given to him intravenously to quell the symptoms he was experiencing. Ralph Raskas already had an IV in his arm for fluid. He was then given an injection of Metoclopramide. He was never told

that he was receiving an injection of Metoclopramide or that it was associated with neurological side effects.

14. On discharge, Ralph Raskas was prescribed 10 mg of Metoclopramide by mouth four times a day. On May 9, 2015, CVS Pharmacy dispensed 20 Metoclopramide 10 mg tablets with a NDC of 00591246805 (hereinafter "Oral Metroclopramide") to Ralph Raskas.

15. At the time of ingestion, Metoclopramide 10 mg tablets bearing an NDC of 00591246805 was manufactured by Actavis. Ralph Raskas took the 20 pills of Oral Metroclopramide.

16. Ralph Raskas, therefore, used Reglan/Metoclopramide manufactured by Teva Pharmaceuticals USA, Inc. and Actavis.

17. As a direct and proximate result of Ralph Raskas' intravenous use of Teva-manufactured metoclopramide in the Emergency Room and oral use of metoclopramide bearing NDC Code 00591246805 following discharge, Ralph Raskas developed a movement disorder which included symptoms of severe difficulty with uncomfortable sensations in his legs as well as an intense urge to move his legs, which persisted after he stopped the metoclopramide. He also had constant and severe pain in his legs to the point that his toes curled permanently. Ralph noted in his personal journal that he experienced the pain and akathisia in his legs shortly after receiving the injection of metoclopramide in May of 2015. He described the restlessness in his legs as "torture."

18. Ralph Raskas returned to UMKC for his second year in August 2015. Nevertheless, because of his neurological injuries caused by his metoclopramide use, Ralph was unable to continue and took a medical leave from UMKC in September 2015. He had the option to return.

19. Ralph Raskas was later treated at a Movement Disorders Center at Washington

University School of Medicine and was diagnosed with a movement disorder.

20. Paul Kotzbauer, MD, PhD of the Movement Disorders Center at Washington University School of Medicine opined that Ralph Raskas' "symptoms are consistent with restless leg syndrome" and that the "symptoms emerged in the setting of treatment with Reglan which is observed with some cases of RLS."

21. After seeing Dr. Kotzbauer, Ralph Raskas was treated by Dr. Kevin J. Black, MD of Barnes-Jewish Hospital, a neuropsychiatrist specialist in movement disorders. After an examination of his medical records and of the patient Ralph Raskas, Dr. Black found the diagnosis to be "drug-induced acute akathisia."

22. On March 24, 2017, at Mercy Hospital Edgewood Behavioral Health, the following was noted about Ralph Raskas: "Patient's akathesia is so severe he has a difficult time staying in group."

23. Furthermore, in September of 2015, Ralph Raskas made his first attempt to commit suicide by taking pain medication for the incredible pain and akathisia in his legs.

24. While still suffering from the Reglan/metoclopramide-induced neurological injuries as described more fully herein, he subsequently made a second attempt to commit suicide in March of 2016.

25. Finally, while still suffering from Reglan/metoclopramide-induced neurological injuries in December 2016, he made a third attempt to commit suicide on December 22, 2016 where he died. As described more fully herein, his Reglan/metoclopramide-induced neurological injuries caused or contributed to cause his wrongful death on December 23, 2016.

Reglan/Metoclopramide short term use serious health risks, including, but not limited akathisia, Reglan-induced tremors, permanent neurological movement disorders, and ideation of suicide

26. Reglan/metoclopramide is a prescription medication classified as a gastrointestinal stimulant, antiemetic and dopamine antagonist. The drug can come in the form of a tablet (5mg/10mg), an injection, or syrup.

27. Reglan/metoclopramide affects the brain and thereby affects the voluntary movements of a user. The effect typically causes involuntary, repetitive movements, also known as extrapyramidal symptoms (EPS).

28. EPS, includes, but not limited to, tardive dystonia, tardive akathisia, Neuroleptic Malignant Disorder, akathisia, and Reglan-induced tremors.

29. Motor restlessness (akathisia) may consist of feelings of anxiety, agitation, jitteriness, and insomnia, as well as inability to sit still, pacing, foot tapping. Defendant claims "These symptoms may disappear spontaneously or respond to a reduction in dosage." *See*, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cccf04bd-7463-40b8-a41f-cb1093c358d7&audience=consumer#i4i_warnings_id_32f62784-3480-4e4f-949c-6efe296596a9.

30. Furthermore, Reglan/Metoclopramide has also been associated with suicidal ideation. Indeed, Reglan/Metoclopramide has been associated with central nervous system disorders, depression with suicidal ideation, visual disturbances, and memory loss. *See, e.g.*, Eilif Dahl, Arthur L. Diskin, Long-lasting adverse effects after treatment with metoclopramide for vomiting. Int Marit Health 2014; 65, 1: 16–19 at 17. ("The fourth day she took 10 mg metoclopramide in the evening, and shortly after she had irrational, compulsive suicidal thoughts that terrified her; she felt her heart racing and had strange somatic sensations, but at that point she believed that her symptoms were caused by the medication.") *See also*, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cccf04bd-7463-40b8-a41f-cb1093c358d7&audience=consumer#i4i_warnings_id_32f62784-3480-4e4f-949c-6efe296596a9

("Mental depression has occurred in patients with and without prior history of depression. Symptoms have ranged from mild to severe and have included suicidal ideation and suicide. Metoclopramide should be given to patients with a prior history of depression only if the expected benefits outweigh the potential risks.") *See also,* https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cccf04bd-7463-40b8-a41f-cb1093c358d7&audience=consumer#i4i_warnings_id_32f62784-3480-4e4f-949c-6efe296596a9 ("Depression, thoughts about suicide, and suicide. Some people who take metoclopramide become depressed. You may have thoughts about hurting or killing yourself. Some people who take metoclopramide have ended their own lives (suicide).")

31. Metoclopramide has been linked to akathisia in many reports and the incidence of restlessness reported after IV administration of drug is 20–25%. Chauhan G, Nayar P, Kashyap C. Metoclopramide-induced akathisia. J Anaesthesiol Clin Pharmacol. 2012 Oct-Dec; 28(4): 548–549.

32. According to "Acute Akathisia Following Intravenous Push of Metoclopramide," available in Journal of Experimental and Clinical Medicine, J Exp Clin Med 2013;5(2):83–84 at 83 a patient was prescribed metoclopramide 10 mg (intravenous) i.v. drip over 15 minutes by the attending physician to relieve symptoms; however, the patient was administered with an i.v. bolus of metoclopramide over 1 minute. *Id.* The symptoms did not improve the next day, and he was administered with metoclopramide 10 mg by i.v. push every eight hours. *Id.* Soon after the third dose of metoclopramide was administered, the patient exhibited involuntary movement and restlessness. *Id.* The physician suspected akathisia induced by metoclopramide. *Id.*

33. It has been reported that the central dopaminergic receptor antagonism of metoclopramide causes extrapyramidal side effects such as akathisia, asthenia, dystonia,

parkinsonism, tardive dyskinesia, and neuroleptic malignant syndrome.[1234] Acute Akathisia Following Intravenous Push of Metoclopramide, J Exp Clin Med 2013;5(2):83–84 at 83.

34. Akathisia and dystonia appear at the early course of metoclopramide treatment. *Id.* In contrast, parkinsonism and tardive dyskinesia showed delayed onset following weeks of treatment with metoclopramide.[5] *Id.*

35. The syndrome of akathisia involves various involuntary actions such as foot or hand movements, inability to keep still while sitting or standing. Acute Akathisia Following Intravenous Push of Metoclopramide, J Exp Clin Med 2013;5(2):83–84. Furthermore, patient may feel restless and urge to move. *Id.*[6]

36. It has been reported that the incidence and severity of akathisia is related to the infusion rate of metoclopramide. *Id.* Three prospective, double blind, and randomized studies have demonstrated that the slow intravenous infusion of metoclopramide over 15 minutes significantly reduces incidence and severity of akathisia compared with fast intravenous bolus over two minutes.[78] *Id.*

37. Furthermore, the infusion rate of metoclopramide does not affect its therapeutic effect

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1 Van Gool AR, Doorduijn JK, Seynaeve C. Severe akathisia as a side effect of metoclopramide. Pharm World Sci 2010;32:704–6.
2 Qiu LM, Lim BL. Case of acute akathisia from intravenous metoclopramide. Singapore Med J 2011;52:e12–4
3 Moos DD, Hansen DJ. Metoclopramide and Extrapyramidal symptoms: a case report. J Perianesth Nurs 2008;23:292–9.
4 Miller LG, Jankovic J. Metoclopramide-induced movement disorders. Clinical findings with a review of the literature. Arch Intern Med 1989;149:2486–92
5 Pasricha PJ, Pehlivanov N, Sugumar A, Jankovic J. Drug insight: from disturbed motility to disordered movement - a review of the clinical benefits and medicolegal risks of metoclopramide. Nat Clin Pract Gastroenterol Hepatol 2006;3: 138–48.
6 *See also* Sachdev P. A rating scale for acute drug-induced akathisia: development, reliability, and validity. Biol Psychiatry 1994;35:263–717
7 Parlak I, Atilla R, Cicek M, Parlak M, Erdur B, Guryay M, Sever M, et al. Rate of metoclopramide infusion affects the severity and incidence of akathisia. Emerg Med J 2005;22:621–4.
8 Regan LA, Hoffman RS, Nelson LS. Slower infusion of metoclopramide decreases the rate of akathisia. Am J Emerg Med 2009;27:475–80.

on alleviation of nausea.[9] *Id.*

38. This adverse drug reaction can be prevented by slowing down the rate of intravenous infusion by following the instruction of the attending physician. *Id.*

39. Raskas is not the only person who has suffered long term physical effects and psychological effects following short term use of Metoclopramide. *See, e.g.*, Eilif Dahl, Arthur L. Diskin, Long-lasting adverse effects after treatment with metoclopramide for vomiting. Int Marit Health 2014; 65, 1: 16–19.

40. The authors in Long-Lasting Adverse Effects After Treatment With Metoclopramide For Vomiting describe a patient who received both intramuscular metoclopramide and intramuscular diphenhydramine at the same time because of vertigo, nausea and vomiting. Eilif Dahl, Arthur L. Diskin, Long-lasting adverse effects after treatment with metoclopramide for vomiting. Int Marit Health 2014; 65, 1: 16–19. She was given intramuscular metoclopramide 10 mg. *Id.* at 17. Immediately after the injections she felt very tired and confused. *Id.* The vomiting stopped, but vertigo persisted. *Id.*

41. The dizziness was treated with 10mg metoclopramide tablets were prescribed twice a day. *Id.* at 17. Metoclopramide was stopped after 4 days, during which she had taken a total of 40 mg (10 mg intramuscular + 30 mg by mouth). *Id.* Shortly after taking only 1/2 tablet (5 mg), she felt faint and anxious, but brushed this off as 'just being sick'. *Id.* After taking another 5 mg at night she felt very anxious, dizzy and weak, but also like her body was about to explode. *Id.* The next day she felt just as bad, thought she was still seasick and took 5 mg metoclopramide twice that day. *Id.* The third day she did not take any metoclopramide. *Id.* The fourth day she took 10 mg metoclopramide in the evening, and shortly after she had irrational, compulsive suicidal thoughts

9 Tura P, Erdur B, Aydin B, Turkcuer I, Parlak I. Slow infusion metoclopramide does not affect the improvement

that terrified her; she felt her heart racing and had strange somatic sensations, but at that point she believed that her symptoms were caused by the medication. *Id.* Therefore, after a total of 40 mg metoclopramide (10 mg intramuscular + 30 mg by mouth) administered over 4 days, metoclopramide was stopped. *Id.* However, she continued to experience disturbing symptoms that she related to the medication almost every day, including dizziness, anxiety, and depression, as well as involuntary movements (twitches, jerks, ticks, and tremors of the eyelids, tongue, neck, fingers, arms and legs) lasting seconds to minutes. *Id.* She was referred to a neurologist consultant in port who agreed with the ship's diagnosis of adverse metoclopramide effects. *Id.* She had previously been healthy and did not use any medications or drugs. *Id.* At the age of 13 she had been in a serious traffic accident and afterwards received posttraumatic stress syndrome counselling for years. *Id.*

42. For about 10 months after metoclopramide she still experienced anxiety, near-panic attacks, nightmares, fatigue and episodes of depression. *Id.* The involuntary movements were gradually reduced in strength and frequency. *Id.*

43. Furthermore, the European Medicines Agency recommended changes to the use of metoclopramide in July of 2013. *See*, European Medicines Agency recommends changes to the use of metoclopramide, 2013. Changes aimed mainly to reduce the risk of neurological side effects. *See i.d.* The review of metoclopramide was carried out at the request of the French medicines regulatory agency (ANSM), following continued safety concerns over side effects and concerns over efficacy. ANSM asked the CHMP to review the benefits and risks of these medicines in all age groups and to recommend consistent indications across the EU.

44. The European Medicines Agency's Committee on Medicinal Products for Human

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rate of nausea while reducing akathisia and sedation incidence. Emerg Med J 2012;29:108–12

Use (CHMP) has recommended changes to the use of metoclopramide-containing medicines in the European Union (EU), including restricting the dose and duration of use of the medicine to minimize the known risks of potentially serious neurological (brain and nerve) side effects. *See*, European Medicines Agency recommends changes to the use of metoclopramide. EMA/443003/2013 at page 1.

45. In pertinent part, detailed recommendations for patients and healthcare professionals are as follows.

Information to patients:

a. For both adults and children, metoclopramide should only be used for a maximum of 5 days.

b. The recommended maximum dose of the medicine has been lowered in adults to a total of 30 mg a day, and some high dose products will be removed from the market as they will no longer be needed.

Information to healthcare professionals:

a. For adults and children the maximum dose in 24 hours is 0.5 mg per kg body weight; in adults, the usual dose of conventional formulations (all routes) is 10 mg up to 3 times daily.

b. Intravenous formulations with concentrations above 5 mg/ml and suppositories containing 20 mg will also be withdrawn.

c. Intravenous doses should be administered as a slow bolus over at least 3 minutes to reduce the risk of adverse effects.

See, Id. at 2-3.

46. The Agency's recommendations are based on a review of the benefit-risk of metoclopramide-containing products in all indications and populations. This included published studies and meta-analyses on the efficacy of metoclopramide and analyses of reports of suspected adverse reactions. *Id.* at 3.

47. The evidence also indicated efficacy in nausea and vomiting associated with acute

migraine, but seemed to indicate that doses above 10 mg do not result in increased efficacy. *Id.*

48. Extrapyramidal disorders were more likely to occur after several doses, although usually early in treatment, and were less likely at slower infusion rates when metoclopramide was given intravenously. *Id.*

49. Given the known risk of neurological and other adverse effects, particularly in children and young people, the Committee concluded that the indications for metoclopramide should be restricted to those involving short-term use, at a maximum dose of 0.5 mg per kg body weight daily, and where there is sufficient evidence of efficacy. *Id.* at 4.

50. As a direct and proximate result of Ralph Raskas' intravenous use of Teva-manufactured metoclopramide in the Emergency Room and oral use of metoclopramide bearing NDC Code 00591246805 following discharge, Ralph Raskas suffered life-changing, permanent neurologic damage, akathisia, gave him ideation of suicide, and the resulting suicide

51. Plaintiff brings these civil actions for equitable relief, monetary restitution, and/or compensatory and punitive damages for injuries suffered as a direct result of Plaintiff Decedent's use of Reglan and/or metoclopramide.

The duty of generic manufacturers of metoclopramide and The Food and Drug Administration Amendments Act (FDAAA) of 2007 allowed for FDA to change a drug's label without the drug company's prior approval.

52. Since 1985, the Defendants have manufactured, sold, distributed, marketed, and labeled generic metoclopramide. Under the ANDA process, the Code of Federal Regulations ("CFR") *required* the Defendants to submit a label for metoclopramide and metoclopramide HCl, initially identical in all material aspects to the Reference Listed Drug, Reglan, label.

53. Each of the Generic Defendants submitted an Abbreviated New Drug Application (hereinafter "ANDA") to the U.S. Food and Drug Administration, based on representations made by

the Defendants, requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

54. The CFR provides that drug labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug. Under the CFR, the Generic Defendants, as ANDA holders, had a duty to report any information to the FDA bearing on the risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl and propose a stronger warning label to the FDA.

55. According to the FDA, these requirements apply to generic drugs because it is a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.

56. The Defendants therefore breached their duty to the FDA because they failed to effectively communicate the risks and/or prevalence of neurological side effects of metoclopramide to the FDA and propose stronger warning labels. As a result, the medical community, Plaintiff Decedent's physicians, Plaintiff, and other foreseeable users similarly situated were not adequately warned of the risks and/or prevalence of neurological side effects of metoclopramide.

57. Furthermore, on September 27, 2007, the Food and Drug Administration Amendments Act (FDAAA) of 2007 was signed into law.

58. The FDAAA of 2007 provided, *inter alia*, that the FDA now had the power to change a RLD label without the involvement of the drug company.

59. Pursuant to the FDAAA of 2007, the "impossibility" preemption found in PLIVA, Inc. v. Mensing, 131 S.Ct. 2567 (2011) is not applicable to claims arising from post-FDAAA of 2007 ingestion of metoclopramide because the FDA had the power to change the RLD label without the involvement of the drug company, and furthermore, under the FDCA, the Generic Defendants

had a duty to communicate the risks involved with the ingestion of metoclopramide to the FDA.

60. Without an adequate warning as to the risks of short term metoclopramide use, Plaintiff's Decedent agreed to use and did use metoclopramide.

61. The Defendants are liable for failing to warn about the risks involved with metoclopramide use after the FDAAA of 2007.

COUNT I
(Strict Liability: Design Defect)

Comes now Plaintiff and for this Count of Plaintiff's Petition, Strict Liability Design Defect, alleges as follows:

62. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

63. Defendants manufactured, designed, distributed, sold, and/or supplied the Reglan/metoclopramide injected into or ingested by Plaintiff Decedent.

64. The Reglan/metoclopramide as manufactured and supplied by Defendants was defective in design and/or formulation in that, when it left the hands of Defendants, the foreseeable risks of serious harm posed by the product exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

65. Furthermore, the Reglan/metoclopramide was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs and/or formulations existed and could have been utilized. A reasonably prudent manufacturer would not have placed the product in the stream of commerce with knowledge of these design and/or formulation flaws.

66. The foreseeable risks associated with the design and/or formulation of the Reglan/ metoclopramide include, but are not limited to, the fact that its design and/or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or

reasonably foreseeable manner because the Reglan/metoclopramide can cause permanent neurological movement disorders as well as injuries such as and ideation of suicide and the resulting suicide.

67. Defendants' conduct was outrageous due to evil motive or reckless indifference to Plaintiff Decedent's safety, justifying an award of punitive damages.

68. WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT II
(Strict Liability: Failure to Warn)

COMES NOW Plaintiff and for this Count alleges as follows:

69. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

70. The Reglan/metoclopramide, as designed, manufactured and/or supplied by Defendants, was defective and unreasonably dangerous when it left the possession of Defendants in that this product contained warnings insufficient to alert consumers of the serious health risks, including, but not limited akathisia, Reglan-induced tremors, permanent neurological movement disorders, and injuries such as ideation of suicide – and the resulting suicide.

71. Defendants knew, or should have known, that their Reglan/metoclopramide created significant risks of serious bodily harm to consumers and Defendants failed to adequately warn Plaintiff Decedent and/or their healthcare providers of serious health risks, including, but not limited to akathisia,, Reglan-induced tremors, permanent neurological movement disorders, and ideation of

suicide, and resulting suicide.

72. Defendants' failure to warn also arises from the breach of their duty to the FDA to effectively communicate the risks and/or prevalence of neurological side effects of metoclopramide to the FDA and propose stronger warning labels.

73. The Reglan/metoclopramide, as designed, manufactured and supplied by Defendants, was defective due to inadequate warning or instruction because after Defendants knew, or should have known, of the risk of serious bodily harm from the Reglan/metoclopramide as described herein, Defendants failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

74. As a direct result of Defendants' failure to warn, Plaintiff Decedent suffered personal injuries, which caused or contributed to cause his personal injuries and wrongful death.

75. Defendants' conduct was outrageous due to evil motive or reckless indifference to Plaintiff Decedent's safety, justifying an award of punitive damages.

76. WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT III
(Negligent Design)

COMES NOW Plaintiff and for this Count, Plaintiff alleges as follows:

77. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

78. Defendants designed, produced, and injected into the stream of commerce, in the

ordinary course of business, Reglan/metoclopramide.

79. At the time the Reglan/metoclopramide was designed, produced and injected into the stream of commerce, this product was defective in design and unreasonably dangerous when put to a reasonably anticipated use, subjecting users to risks of the Reglan/metoclopramide causing permanent neurological movement disorders as described herein and causing or contributing to cause his personal injuries and wrongful death.

80. Plaintiff Decedent's injuries caused by Defendants' Reglan/metoclopramide were completely foreseeable and could or should have been anticipated by Defendants.

81. Defendants' metoclopramide reached Plaintiff Decedent and others without substantial change and Plaintiff Decedent was unaware of the dangerousness of the Reglan/metoclopramide until after Plaintiff Decedent had ingested it and developed tardive dyskinesia.

82. Defendants knew or should have known that the Reglan/ metoclopramide posed a serious risk of bodily harm and injury to consumers.

83. Defendants had a duty to establish reasonable quality systems for the design of the Reglan/ metoclopramide, including a duty to assure that the product did not pose a significantly increased risk of bodily harm and adverse events.

84. In particular, Defendants should have discontinued the use of Reglan/ metoclopramide injections for teenagers that present with symptoms of vomiting and nausea considering the neurological risks of the Reglan/ metoclopramide as described herein.

85. In designing the Reglan/metoclopramide, Defendants failed to exercise ordinary care and caution for the safety, health and welfare of Plaintiff Decedent in one or more of the following respects:

a. Defendants knew, or should have known, that there were safer, alternative designs and/or formulations that would minimize the risk of neurological movement disorders: notably as to Defendants, the utility of the Reglan/ metoclopramide injections for teenagers that present with symptoms of vomiting and nausea is outweighed by the risk of neurological injury as described herein; and

b. such other acts and/or omissions as may be shown proper at the time of trial.

86. As a direct result of Defendants' failure to exercise the ordinary care that a careful and prudent manufacturer would exercise when Defendants designed the Reglan/ metoclopramide, Plaintiff Decedent suffered personal injury, which caused or contributed to cause his personal injuries and wrongful death.

87. Defendants demonstrated a conscious disregard for Plaintiff Decedent's safety, justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT IV
(Negligent Failure to Warn)

Comes now Plaintiff and for this Count of Plaintiff's Petition, Negligent Failure to Warn, alleges as follows:

88. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

89. Defendants had a duty to establish reasonable quality systems for the design,

production, and distribution of the Reglan/metoclopramide into the stream of commerce, including a duty to assure that the product did not pose a significantly increased risk of bodily harm and adverse events.

90. Defendants had a continuing duty to warn consumers, including Plaintiff Decedent and Plaintiff Decedent's treating physicians, about the Reglan/metoclopramide and the risks and dangers associated with it, including but not limited to serious health risks, including, but not limited to akathisia,, Reglan-induced tremors, permanent neurological movement disorders, ideation of suicide, and resulting suicide as described herein.

91. By negligently and/or wantonly failing to adequately warn of the danger of using the Reglan/metoclopramide, the Defendants breached their duty by:

a. failing to include adequate warnings with the Reglan/metoclopramide that would alert consumers and doctors to the dangerous risks of the Reglan/metoclopramide as described herein;

b. failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of the Reglan/metoclopramide causing permanent neurological movement disorders as described herein;

c. failing to inform Plaintiff Decedent and Plaintiff Decedent's treating physicians that the Reglan/metoclopramide had not been adequately and thoroughly tested as described herein;

d. failing to effectively communicate the risks and/or prevalence of neurological side effects of metoclopramide to the medical community, Plaintiff Decedent's physicians, Plaintiff Decedent and other like foreseeable users.

92. The Defendants negligently and/or wantonly failed to adequately warn of the danger of using Reglan/metoclopramide by failing to effectively communicate the risks and/or prevalence of neurological side effects of metoclopramide as described herein to the FDA and propose stronger

warning labels as required by the FDA schema, thereby breaching their duty.

93. Despite the fact that Defendants knew or should have known that the Reglan/metoclopramide posed a serious risk of bodily harm and injury to consumers, Defendants continued to manufacture and market the metoclopramide for use by consumers and Defendants knew or should have known that consumers such as Plaintiff Decedent would foreseeably suffer serious injury as a result of Defendants' failure to exercise ordinary care as described above.

94. As a direct result of Defendants' failure to provide adequate warnings and failure to adequately test the Reglan/metoclopramide, Plaintiff Decedent suffered personal injury and economic harm, for which Plaintiff seeks just compensation herein.

95. Defendants demonstrated a conscious disregard for Plaintiff Decedent's safety, justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT V
(Negligence)

Comes now Plaintiff and for this Count of Plaintiff's Petition, Negligence, alleges as follows:

96. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

97. Defendants had a duty to establish reasonable quality systems for the design, production, distribution and/or sale of the metoclopramide ingested by Plaintiff.

98. The quality systems must encompass an adequate organizational structure to ensure

that a quality policy for the Reglan/metoclopramide is implemented and maintained at all levels of the organization and adequate quality control audits are carried out.

99. The quality system must establish adequate design controls, design input, design output, design review, design verification, design validation, and design transfer procedures with adequate documentation and document controls.

100. Defendants should have also enacted a post-sale surveillance procedure to adequately identify problems with the Reglan/metoclopramide after sale to determine whether problems have developed with the product such that a reasonably prudent manufacturer would make design and/or formulation or manufacturing changes or investigate incidents where patients developed neurological movement disorders.

101. Defendants breached the standard of care of an ordinarily careful and prudent manufacturer of Reglan/metoclopramide because Defendants had not implemented adequate manufacturing processes and post-surveillance sales processes to identify the increased serious health risks, including, but not limited to akathisia, Reglan-induced tremors, permanent neurological movement disorders, ideation of suicide, and resulting suicide in patients using Reglan/metoclopramide.

102. Defendants, based on incidents where Reglan/metoclopramide caused permanent neurological disorders, had notice of this problem and knew or should have known of it.

103. As a direct and proximate result of Defendants' negligence, Plaintiff Decedent suffered personal injury and economic harm, for which Plaintiff seeks just compensation herein.

104. Defendants demonstrated a conscious disregard for Plaintiff Decedent's safety, justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT VII
(Negligence/Violation of FDA requirements)

Comes now Plaintiff and for this Count of Plaintiff's Petition, Negligence/Violation of FDA requirements, alleges as follows:

105. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

106. As set forth above, the Defendants, failed to modify their metoclopramide labels to warn that the injection of metoclopramide could lead to serious health risks, including, but not limited to akathisia, Reglan-induced tremors, permanent neurological movement disorders, ideation of suicide, and resulting suicide.

107. Defendants, failed to modify their metoclopramide labels to warn that the ingestion of metoclopramide could lead to serious health risks, including, but not limited to akathisia, , Reglan-induced tremors, permanent neurological movement disorders, ideation of suicide, and resulting suicide.

108. Without this knowledge, physicians continued prescribing metoclopramide and Plaintiff Decedent continued prescribe metoclopramide for short term use.

109. The Defendants had a duty to update their label in accordance with what the EU findings described an indicated above as well as the information in Defendants' possession about the dangers of metoclopramide even for a short period of time.

110. As a direct result of the Defendants' failure to update their label as allowed by the

FDA, Plaintiff Decedent suffered personal injury and economic harm, for which Plaintiff seeks just compensation herein.

111. The Defendants demonstrated a conscious disregard for Plaintiff Decedent's safety, justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for:

A. Actual damages;

B. Punitive damages;

C. Costs herein incurred; and

D. Such other legal and equitable relief that this Court deems just and proper.

COUNT VI
(Wrongful Death Pursuant to RSMo § 537.080 and 537.090)

COMES NOW Plaintiff, individually, by and through counsel, and for this Count against the defendants, and each of them, allege and state as follows:

112. Plaintiff hereby incorporates by reference into this Count each and every paragraph set forth in this Petition as if fully set forth herein.

113. As Plaintiff is the Natural Father of Decedent Ralph Raskas, he is a proper party under Missouri's Wrongful Death Statute to bring this cause of action against defendants.

114. Defendants committed the wrongful acts and omissions set forth more fully in this Petition.

115. As a direct and proximate result of the wrongful acts and omissions of the Defendants, and each of them, jointly and severally, as set forth above, Plaintiff Decedent received the following severe, permanent, devastating and progressive injuries which caused or contributed to cause Plaintiff's Decedent's wrongful death as described more fully herein.

116. As a direct and proximate result of defendants' wrongful acts and omissions, and each

of them, the decedent was caused to suffer great mental pain and suffering prior to his death.

117. As a direct and proximate result of the wrongful acts and omissions of the Defendants, and each of them, as alleged above, Plaintiff has been forced to expend monies for decedent's medical treatment prior to his death, funeral, and burial expenses and other expenses the amount of which is presently unknown with exactitude by the Plaintiff; Plaintiff has been forever deprived of the decedent's services, consortium, comfort, companionship, instruction, guidance, counsel, training and support and has forever lost the benefits derived from any past and future income provided by Plaintiff's Decedent.

118. As a further direct and proximate result of the wrongful acts and omissions of the Defendants, and each of them, the Plaintiff's Decedent was caused to suffer great mental pain and suffering prior to his death, all to Plaintiff's damage in an amount which Plaintiff at this time is unable to state with exactitude.

WHEREFORE, Plaintiff prays judgment against the defendants, and each of them, jointly and severally, acting by and through the other, for such damages for the Wrongful Death of Plaintiff Decedent as are fair and reasonable, together with any and all costs herein incurred and expended and for such other relief as this Court may deem just and proper.

COUNT VII
(Loss of Consortium)

COMES NOW Plaintiff, individually, and for his cause of action for loss of consortium against the Defendants, alleges and states as follows:

2. Plaintiff hereby incorporates by reference into this Count each and every paragraph set forth in this Petition as if fully set forth herein.

3. Plaintiff is, and was at all times mentioned, the Father of Plaintiff Decedent.

4. As a direct and proximate result of the negligence and carelessness of the Defendants,

jointly and severally, and each of them, and of the damages sustained by Plaintiff Decedent, Plaintiff has been deprived of Plaintiff Decedent's valuable services and support, as well as her comfort, society, companionship, consortium, love, affection, advice and counsel.

5. Plaintiff has been obligated for medical and other expenses due to his son's condition. Plaintiff's son has suffered an untimely and agonizing death due to Defendants' negligence.

CAREY, DANIS & LOWE

By: /s/ Francis J. Flynn, Jr.

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